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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,500	11/21/2003	Timothy B. Hibler	THIBL.001A	3027

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,500	<b>Applicant(s)</b> HIBLER, TIMOTHY B.	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 3 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-10,13-26,28-40 and 42-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-46 is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-10,13-26,28-40 and 47-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 3 October 2005 have been fully considered but they are not persuasive. The Applicant argues that Nobles et al. does not teach wherein the anchoring feature is an uneven outer surface of the expandable mechanism when it is expanded. The Examiner disagrees. The device taught by Nobles in FIG. 1 is a balloon. The elongated member and expandable mechanism as a whole is a balloon. The device of Nobles et al. reads on the claim because the elongated member is part of the expandable member. The elongated member is expandable [0055]. The expandable elongated member has an uneven surface. The uneven surface makes contact with a body cavity and therefore helps anchor the device.
2. The same goes for the embodiment shown in FIG. 8A. The device as a whole is a balloon. Because the device as an expandable mechanism, the elongated member is also expandable. As shown in FIG. 8A the outer surface of the device is uneven.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

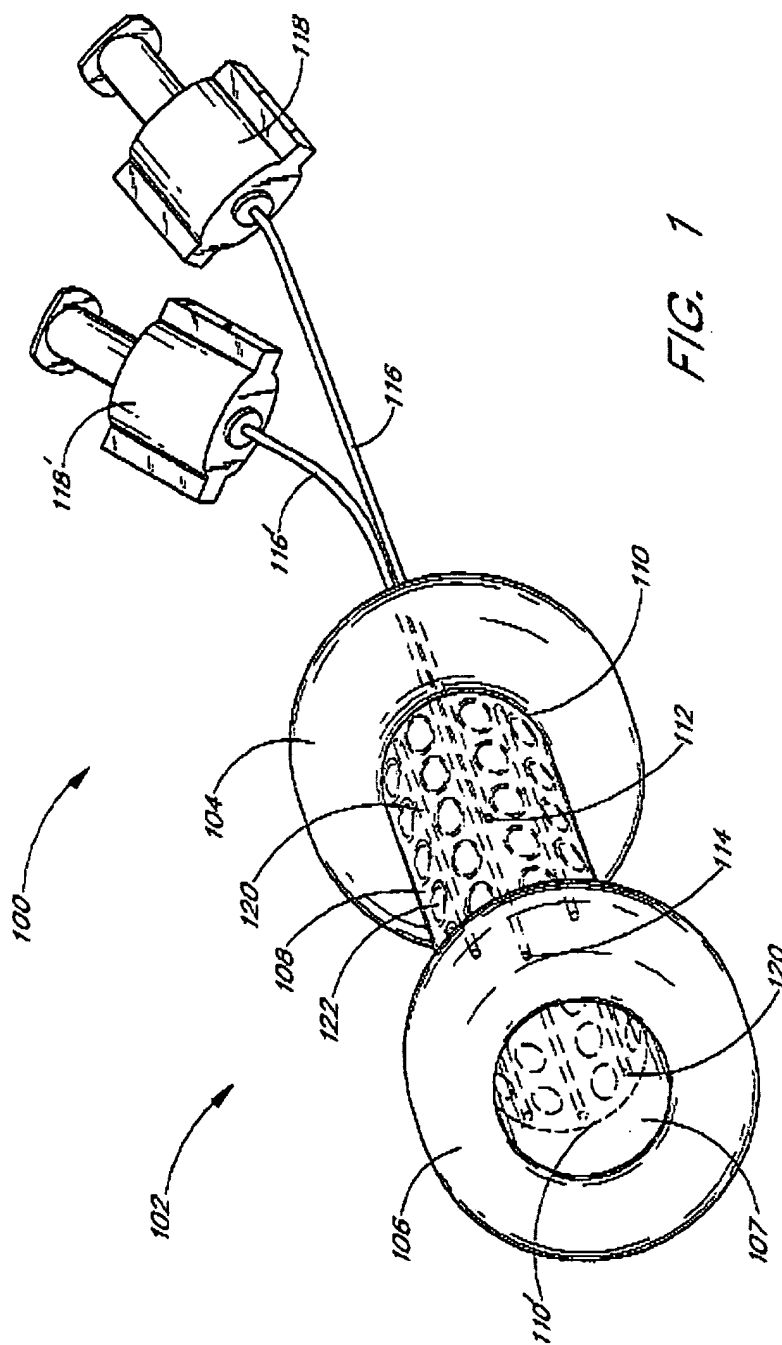
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1, 4-6, 8-10, 13-26, 28, 31-39, and 47-54 are rejected under 35

U.S.C. 102(e) as being anticipated by Nobles et al. US 2002/0013601 A1.

5. As to claims 1-8, Nobles et al. teaches a cervical medical device, comprising: an elongated member; an expandable mechanism attached to the elongated member; an anchoring feature; wherein the anchoring feature is deployable component attached to the elongated member distally of the expandable mechanism; wherein the anchoring feature is an uneven outer surface of the expandable mechanism when it is expanded; wherein the expandable mechanism is a corrugated balloon; wherein the expandable mechanism is a ridged balloon; wherein the elongated member comprises a lumen running through a length of the device; wherein the anchoring feature and the expandable mechanism are independently inflatable balloons [0070]; wherein the anchoring feature is a series of spaced ridges along a length of the expandable mechanism.



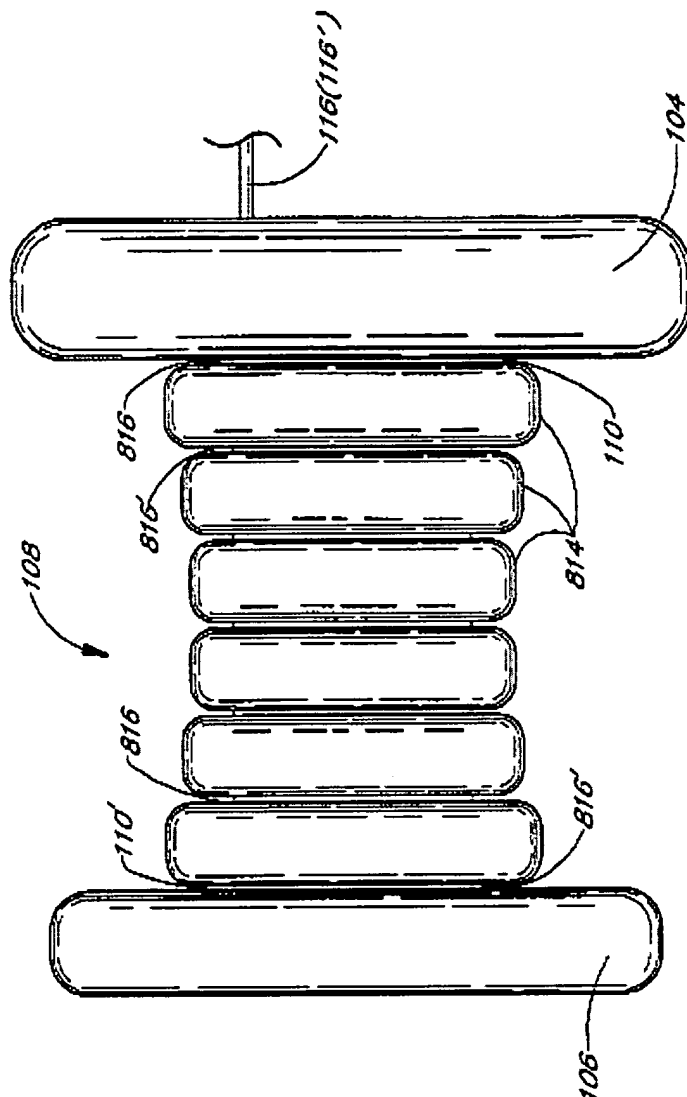
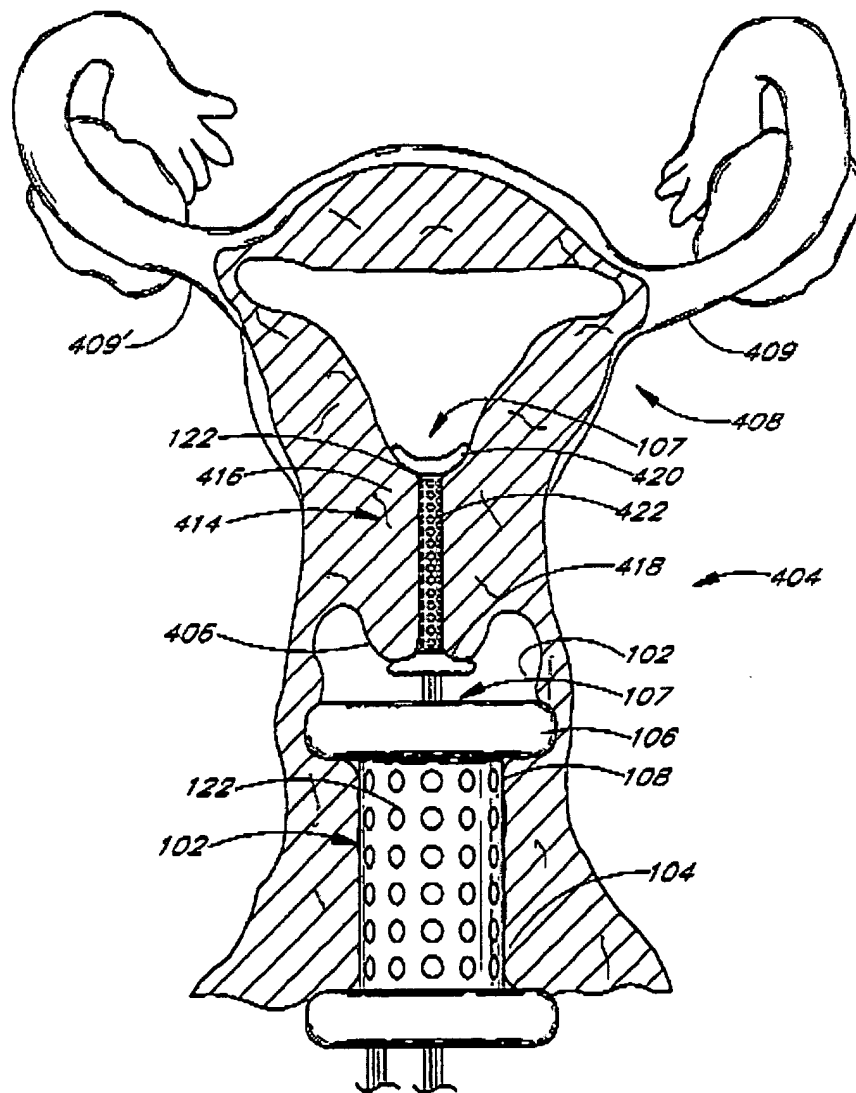


FIG. 8A

6. As to claims 9, 10, and 13-17, Nobles et al. teaches a cervical anchoring method, comprising: inserting a hollow tube into a cervical canal; inserting at least one expandable dilator into the cervical canal; radially expanding the at least one expandable dilator within the canal to dilate the cervical canal while the tube is in the canal, wherein the at least one expandable dilator has an uneven surface; wherein the at least one expandable dilator is attached to the outer surface of the hollow tube; wherein the wherein the at least one expandable dilator has a corrugated outer surface;

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wherein the at least one expandable dilator has an uneven outer surface; wherein the at least one expandable dilator has a ridged outer surface; wherein the at least one expandable dilator comprising a series of two balloons along the tube; wherein the series of two balloons comprises an anchor balloon distally of a dilating balloon.



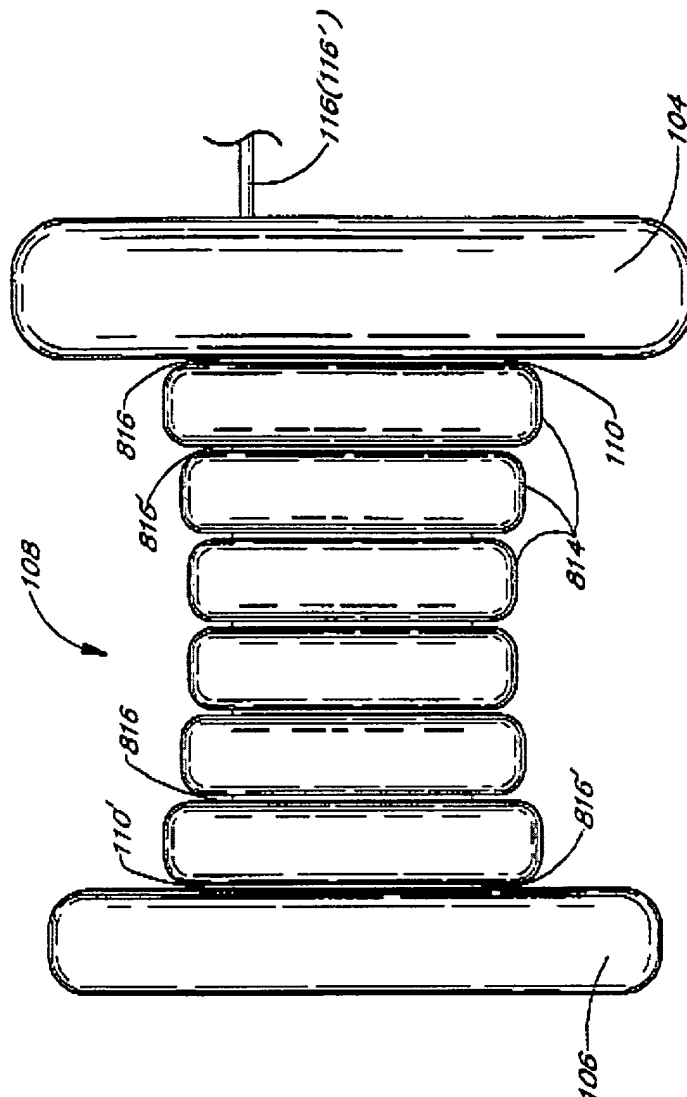


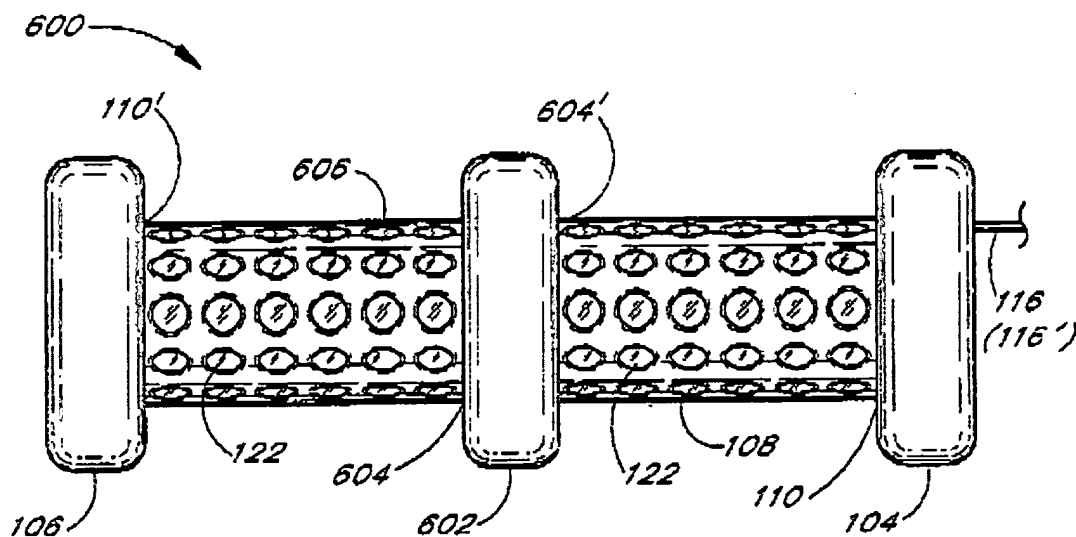
FIG. 8A

7. As to claims 18-28, Nobles et al. teaches a cervical dilating device, comprising: an elongated member having a proximal end and a distal end; a first expandable component attached to the distal end of the elongated member; a second expandable component attached to the elongated member proximally of the first expandable component, wherein the second expandable component has an uneven outer surface; wherein the elongated member comprises a lumen running the entire length of the device; an expansion mechanism coupled to the first and second expandable



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components, wherein the expansion mechanism is a fluid-filled syringe; wherein the expansion mechanism is a gas-filled syringe [0070]; wherein the first and second expandable components are inflatable balloons; wherein the first expandable component is a rounded balloon and the second expandable component is a cylindrical balloon; wherein the first and second expandable components are adjustable between a radially collapsed condition and a radially expanded condition (fig. 16A & 16B); an optical imaging component in the elongated member [0066]; and wherein the second expandable member has a length between 40 millimeters and 100 millimeters when expanded [0056].

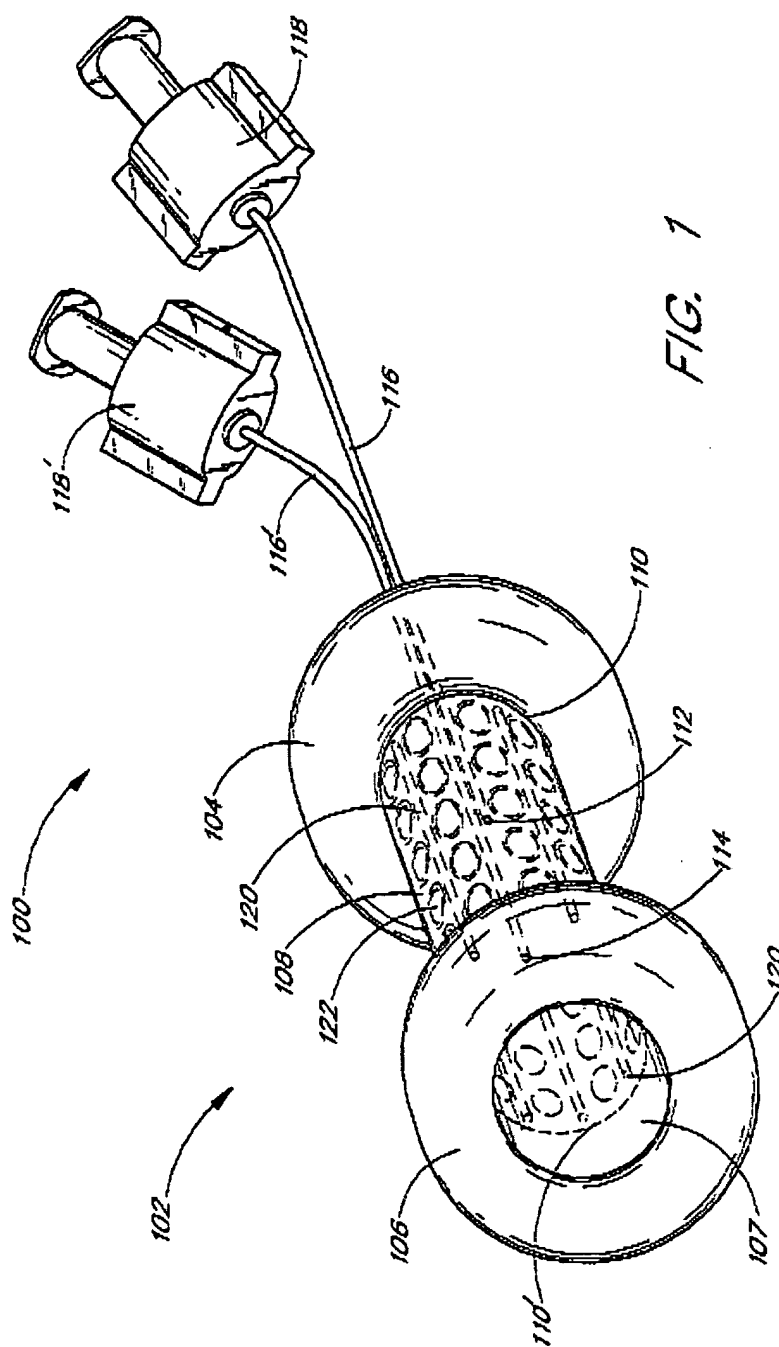


**FIG. 6**

8. As to claims 31-39 and 41, Nobles et al. teaches a cervical sealing device, comprising: an elongated member having a proximal end and a distal end; an expandable seal assembly attached to the elongated member, wherein the seal assembly has an uneven outer surface in an expanded condition; wherein the elongated

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member comprises a lumen running through a length of the device; an expansion mechanism coupled to the seal assembly; wherein the expansion mechanism is a fluid-filled syringe; wherein the expansion device is a gas-filled syringe [0070]; wherein the seal assembly has a length between 40 millimeters and 100 millimeters when expanded [0056]; wherein the seal assembly has a diameter between 5 millimeters and 20 millimeters when expanded [0056]; wherein the seal assembly is a corrugated balloon; wherein the seal assembly is a balloon having a series of evenly spaced ridges along its length; wherein the seal assembly is a dimpled balloon.



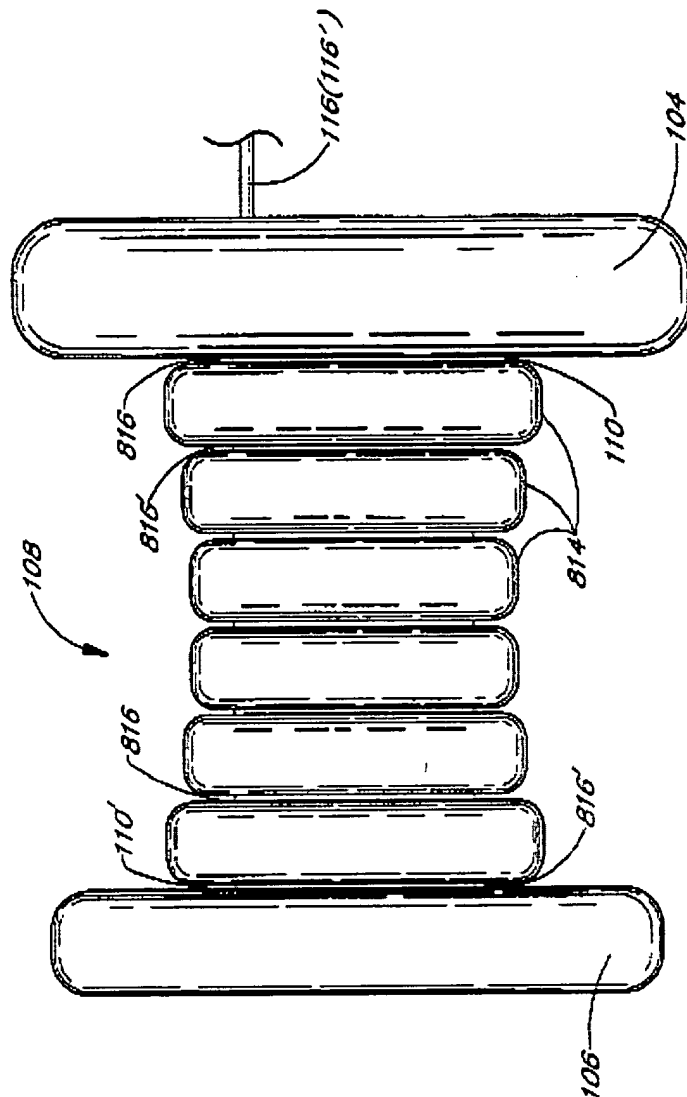
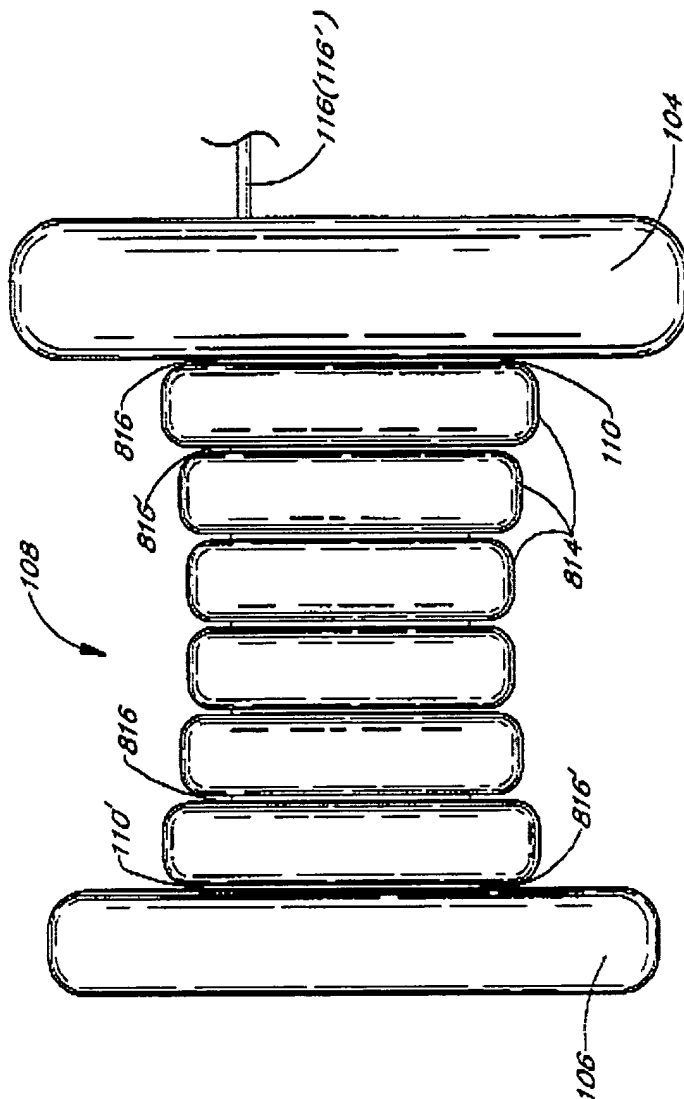


FIG. 8A

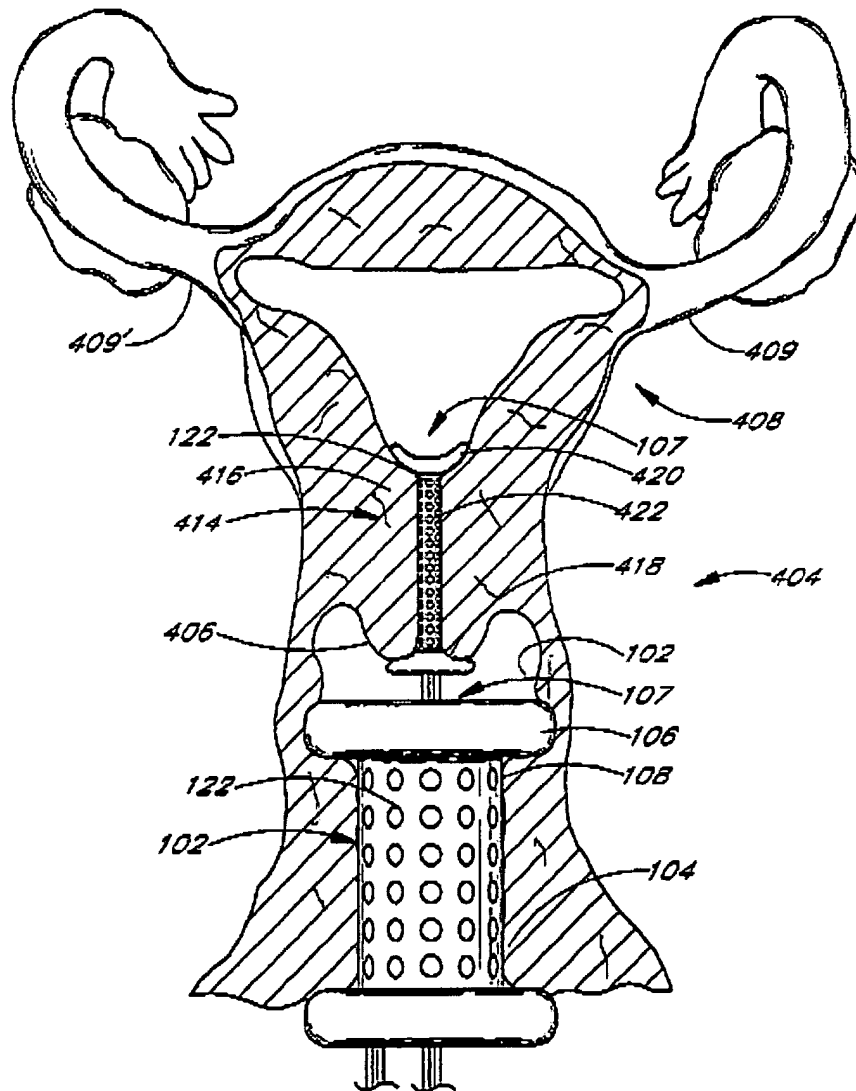
9. As to claims 47-51, Nobles et al. teaches a method of sealing a cervical canal, comprising: introducing a sealing device in the cervical canal, the device comprising a tube and an expandable seal assembly attached to the tube, wherein the seal assembly has an uneven outer surface when it is expanded; and expanding the seal assembly after introducing; wherein the device further comprises an expansion mechanism; wherein expanding comprises filling a balloon with a fluid [0070]; wherein the seal

assembly is a balloon having a series of spaced ridges along its length; and wherein the seal assembly is a corrugated balloon.



10. As to claims 52-54, Nobles et al. teaches a method of providing a seal for a cervical canal, comprising: inserting a cervical sealing device into the cervical canal, the device comprising a cannula (116 & 116') having a plurality of valves (118 & 118'), and a inflatable balloon attached to the cannula, wherein the balloon has an uneven surface when inflated; and inflating the balloon while the device is in the cervical canal

(fig. 4 & 4A); wherein the device further comprises an obturator; removing the obturator after the cannula is inserted (figs. 16-20B).



### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 29, 30, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobles et al.

13. As to claims 29 and 30, Nobles et al. teaches the device of claim 18 except for the claimed diameter ranges of the second expandable member when expanded and collapsed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range limitations, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, USPQ 233. Furthermore, Nobles et al. teaches that the size of the apparatus is to be selected to conform to the anatomy of the surrounding tissue of the particular organ, lumen or body cavity [0054].

As to claim 40, Nobles teaches the device of claim 49 except for wherein the balloon has between 3 and 4 ridges. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the number of ridges as recited in the claim because the particulars of the number of ridges is a mere design choice obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of the dimensions are of importance or solve a stated problem or provide an advantage over the prior art.

***Allowable Subject Matter***

14. Claims 42-46 are allowable over the prior art of record.

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15. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach or render obvious the method of dilating a cervical canal, comprising: inserting a dilating device into the cervical canal, the dilating device comprising a second expandable component having an uneven outer surface; expanding a first expandable component; retracting the dilating device until resistance is felt while the first expandable component is expanded; and expanding the second expandable component in the cervical canal after retracting.

### ***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM



GLENN K. DAWSON  
PRIMARY EXAMINER